DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-459/S-002

Baxter Pharmaceutical Products Inc.
95 Spring Street
New Providence, New Jersey 07974

Attention: Priya Jambhekar
Director, Regulatory Affairs

Dear Ms. Jambhekar:

Please refer to your supplemental new drug application dated December 4, 2000, received December 5, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Revex (nalmefene HCl injection).

We acknowledge receipt of your submission dated December 4, 2000.

This supplemental new drug application originally proposed revisions to the "Duration of Action" subsection of the DOSAGE AND ADMINISTRATION section of the package insert. In response to our November 7, 2000, approvable letter, the revision has been deleted. The final printed labeling submitted December 4, 2000, contains editorial revisions that were implemented in 1999.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Shepherd, Project Manager, at (301) 827-7430.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research